

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of) Examiner: Not Assigned
Burbank, et al.) Group Art Unit: Not Assigned
For: **BIOPSY ANCHOR DEVICE WITH**) Customer No.: 23422
CUTTER)
Serial No.: Not Assigned) **PRELIMINARY AMENDMENT AND**
Filed: December 28, 2001) **INFORMATION DISCLOSURE**
Docket No.: 9619-1191) **STATEMENT**

Express Mail Label No.: EF 401141456US
Mailed on January 23, 2002

BOX PATENT APPLICATION
Commissioner for Patents
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Sir:

This is a continuation of the copending application Serial No. 09/753,529, filed December 28, 2000, of Burbank et al., for **BIOPSY ANCHOR DEVICE WITH CUTTER**, being examined in Group Art Unit 3736 by Examiner M. Hindenburg. Please amend the above-identified application as follows:

IN THE SPECIFICATION

Please amend the paragraph beginning on page 1, line 3 to read:

The present invention is a continuation of United States Patent Application Serial No. 09/753,529 for "Biopsy Anchor Device with Cutter," filed on December 28, 2000, and a continuation-in-part of United States Patent Applications Serial Nos. 09/057,303 for "Breast Biopsy System and Method," filed on April 8, 1998, now United States Patent No. 6,331,166; 09/146,185 for "Methods and Apparatus for Securing Medical

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Instruments to Desired Locations in a Patient's Body," filed on September 1, 1998; 09/159,467 for "Electrosurgical Biopsy Device and Method," filed on September 23, 1998, now United States Patent No. 6,261,241; 09/238,965 for "Tissue Specimen Destruction Device and Method Thereof," filed on January 27, 1999; 09/356,187 for "Electrosurgical Lesion Location Device," filed on July 16, 1999, now United States Patent No. 6,312,429; and 09/477,255 for "Apparatus and Method for Accessing a Biopsy Site," filed on January 4, 2000, all assigned to the assignee of the subject application, which are each hereby incorporated by reference in their entirety, and from each of which priority is claimed under 35 U.S.C. 120.

Please amend the paragraph beginning on page 12, line 14 to read:

Figure 2A is a perspective view of a device with radial wires and side-cutting wire electrode retracted; Figure 2B a perspective view of a device with radial wires extended; Figure 2C a perspective view of a device with radial wires and side-cutting electrode extended; and Figure 2D a perspective view of a device with the side-cutting electrode extended.

Please amend the paragraph beginning on page 12, line 19 to read:

Figure 3A a perspective view of a wand with radial wires and side-cutting electrode retracted; Figure 3B a perspective view of a wand with radial wires and side-cutting electrode extended; Figure 3C is a partially cut-away view of a handle embodying features of the invention, showing a plunger mechanism embodying features of the invention with a plunger extended; and Figure 3D is a partially cut-away

view of a handle embodying features of the invention, showing a plunger mechanism embodying features of the invention with a plunger depressed.

Please amend the paragraph beginning on page 13, line 3 to read:

Figure 4A is a partly cut-away perspective view of the distal tip of the wand particularly showing an electrosurgical electrode. Figures 4B and 4C are perspective views of the distal portion of the wand showing extended radial wires and an extended side-cutting electrode illustrating features of the invention.

Please amend the paragraph beginning on page 13, line 9 to read:

Figures 5A and 5C are longitudinal cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention, and Figures 5B, and 5D-F are transverse cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention.

Please amend the paragraph beginning on page 13, line 13 to read:

Figures 6A and 6C are longitudinal cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention, and Figures 6B and 6D are transverse cross-sectional views of the shaft of the wand illustrating features of the invention showing a side-cutting electrode in retracted (6A, 6B) and extended (6C, 6D) configurations.

Please amend the paragraph beginning on page 13 line 19 to read:

Figures 8A-8F provide partially cut-away perspective views of a surgeon's disposable unit illustrating features of the invention.

Please amend the e paragraph beginning on page 14, line 1 to read:

Fig. 10A-10D, and 10G are partially cut-away side-views of the wand of Figure 1 embodying features of the invention. Figs. 10E-10F are transverse cross-sectional views of the wand of Figure 1 embodying features of the invention and breast tissue during a procedure embodying features of the methods of the invention.

IN THE CLAIMS

Please cancel claims 1-36.

Please add the following new claims:

37. A drive unit for engaging and holding a biopsy device, said biopsy device having a shaft with an end, an electrosurgical electrode secured to said shaft end, at least one deployment mechanism operably connected with a deployable element, said drive unit comprising a receptacle configured to engage and hold said biopsy device, an electrical connector configured to connect to a radiofrequency (RF) power source and to said biopsy device effective to provide an operable electrical connection between said biopsy device and said RF power source, and a mechanical connector configured to transfer mechanical power to said biopsy device.

38. The drive unit of claim 37, wherein said drive unit comprises a disposable device.

39. The drive unit of claim 37, further comprising a drive element configured to engage a shuttle, said shuttle being configured to operably connect to a deployment mechanism of a biopsy device, effective to deploy or retract said deployable element.

40. The drive unit of claim 37, wherein said deployable element is selected from the group of elements consisting of cutting elements and fixation elements, said cutting elements including electrosurgical cutting electrodes, and said fixation elements including fixation wires, wherein said fixation wires may be electrosurgical fixation wires.

41. The drive unit of claim 37, further comprising a drive gear configured to engage a shaft gear effective to rotate a shaft of a biopsy device.

42. The drive unit of claim 37, wherein said mechanical connector further comprises a spindle, and wherein said mechanical power comprises rotary power.

43. A motor unit for engaging and providing power to a drive unit, comprising a securing mechanism effective to form a mechanically stable engagement between said motor unit and said drive unit, and a coupling mechanism configured to engage with a mechanical connector of a drive unit effective to transfer mechanical power.

44. The motor unit of claim 43, wherein said securing mechanism comprises a snap.

45. The motor unit of claim 43, wherein said mechanical power comprises rotary power and said coupling mechanism comprises a ridged sleeve adapted to receive a spindle effective to transfer rotary motion.

46. A system for accessing target tissue within a patient and isolating a body of target tissue from its supporting bed, comprising:

a biopsy device having a wand, said wand comprising:

an elongated shaft having a distal end, a proximal end and a longitudinal axis,

an electrosurgical electrode secured to the distal end of the shaft,

a first electrical conductor extending within the shaft having a distal end electrically connected to the electrosurgical electrode and a proximal end configured to be electrically connected to an electrical power source, and

at least one deployable element connected to said shaft;

a drive unit for engaging and holding at least a portion of a biopsy device having a wand, comprising:

a receptacle configured to engage and hold a biopsy device having a wand, an electrical connector configured to connect to an RF power source and to said biopsy device effective to provide an operable electrical connection between said biopsy device and said RF power source, and

a mechanical connector configured to transfer mechanical power to said biopsy device; and

a motor unit for engaging and providing power to a drive unit, comprising:

a securing mechanism effective to form a mechanically stable engagement between said motor unit and said drive unit, and a coupling mechanism configured to engage with a mechanical connector of a drive unit effective to transfer mechanical power.

47. The system of claim 46, wherein said at least one deployable element is selected from the group consisting of an anchoring mechanism and a side-cutting mechanism comprising a cutting element.

48. The system of claim 47, wherein said anchoring mechanism is located proximal to the distal end of the shaft.

49. The system of claim 47, wherein said cutting element of said side-cutting mechanism is configured to be rotated about the longitudinal axis of the shaft effective to isolate a body of target tissue when said shaft is disposed within a patient.

50. The system of claim 48, comprising an anchoring mechanism and a side-cutting mechanism, wherein said cutting element of said side-cutting mechanism is configured to be rotated about the longitudinal axis of the shaft effective to isolate a body of target tissue when said shaft is disposed within a patient.

51. The system of claim 46, wherein said drive unit further comprises a drive element configured to engage a shuttle effective to deploy or retract a deployable element of said biopsy device.

52. The system of claim 47, wherein said tissue anchoring mechanism comprises a radial wire.

53. The system of claim 46, wherein said drive unit further comprises a drive gear configured to engage a shaft gear effective to rotate said shaft of said wand.

54. The system of claim 46, wherein said mechanical connector of said drive unit further comprises a spindle, and wherein said mechanical power comprises rotary power.

55. The system of claim 46, wherein said securing mechanism of said motor unit comprises a snap.

56. The system of claim 46, wherein said mechanical power of said motor unit comprises rotary power and said coupling mechanism comprises a ridged sleeve configured to receive a spindle effective to transfer rotary motion.

57. The system of claim 50, wherein said cutting element of the side-cutting mechanism of said biopsy device comprises an elongated electrode having a distal end secured distal to the anchoring mechanism and a proximal end secured proximal to the anchoring mechanism and said wand further comprises a second electrical conductor extending within the shaft having a distal end electrically connected to the elongated electrode and a proximal end configured to be electrically connected to an electrical power source.

58. The system of claim 46, wherein said electrosurgical electrode of said biopsy device has a cutting surface spaced distal to the distal end of the shaft.

59. The system of claim 47, wherein said anchoring mechanism of said biopsy device includes a plurality of elongated members configured to expand outwardly from the elongated shaft of the biopsy device and to penetrate into target tissue.

60. The system of claim 59 wherein said elongated members of said anchoring mechanism are formed at least in part of electrically conducting material.

61. The system of claim 60 wherein a third electrical conductor extends within the elongated shaft of the biopsy device and has a distal end electrically connected to at least one of the elongated members and a proximal end configured to be electrically connected to an electrical power source.

62. The system of claim 60 wherein the elongated members of said anchoring mechanism are metallic wires or ribbons.

63. The system of claim 62 wherein the wires or ribbons are movably mounted to the elongated shaft of the biopsy device and have a contracted configuration to facilitate advancement of the biopsy device within the patient and a radially expanded configuration to penetrate into target tissue.

64. A handle for engaging and holding a biopsy device, said biopsy device having a shaft with an end, an electrosurgical electrode secured to said shaft end, a deployable fixation element, said handle comprising a receptacle configured to engage and hold said biopsy device, a mechanical element configured to convey mechanical power to said deployable fixation element, and an electrical connector configured to connect to a radiofrequency (RF) power source and to said biopsy device effective to provide an operable electrical connection between said biopsy device and said RF power source.

65. The handle of claim 64, wherein said mechanical element comprises a plunger configured to aid in the deployment of said deployable fixation element.

66. A system comprising:

a biopsy device having:

a wand comprising an elongated shaft having a distal end, a proximal end and a longitudinal axis,

an electrosurgical electrode secured to the distal end of the shaft,

a first electrical conductor extending within the shaft having a distal end electrically connected to the electrosurgical electrode and a proximal end configured to be electrically connected to an electrical power source,

a tissue anchoring mechanism located proximal to the distal end, and

a side-cutting mechanism having a cutting element configured to be rotated about the longitudinal axis of the shaft and thereby to isolate a body of target tissue; and

10056453.012302 a handle comprising:

a receptacle configured to engage and hold said biopsy device,

a mechanical element configured to convey mechanical power to said deployable fixation element, and

an electrical connector configured to connect to a radiofrequency (RF) power source and to said biopsy device effective to provide an operable electrical connection between said biopsy device and said RF power source.

REMARKS

A marked up copy of the above-described amendments to the specification showing all changes is attached. The amended specification corrects informalities noted by the Examiner during prosecution of the original application.

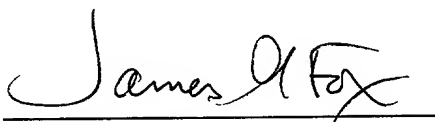
Claims 1-23 are directed to system 10, drive unit 120 and motor unit 130 as disclosed in Figs. 1, 3, 7, and 8 and throughout the specification (e.g., pages 14, second paragraph; page 16-17 (drive unit 120, termed surgeon's disposable unit); page 18, full paragraph (motor unit); page 27-28 bridging paragraph (handle)). No new matter is introduced by way of the amendments or new claims.

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO-1449 forms and request that they be considered by the Examiner. Copies of the references are not enclosed because each of the references was previously submitted to the PTO in prior application Serial No. 09/753,529, filed

December 28, 2000, which is relied upon for an earlier effective filing date under 35 U.S.C. §120. This Information Disclosure Statement is being submitted under 37 C.F.R. § 1.97(b)(1), therefore no fee is due.

Consideration and allowance of the new claims is earnestly solicited.

Respectfully Submitted,



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Version with Markings to Show Changes Made

(Deletions are [bracketed] and additions are underlined.)

IN THE SPECIFICATION

The paragraph beginning on page 1, line 3:

The present invention is a continuation of United States Patent Application Serial No. 09/753,529 for "Biopsy Anchor Device with Cutter," filed on December 28, 2000, and a continuation-in-part of United States Patent Applications Serial Nos. 09/057,303 for "Breast Biopsy System and Method," filed on April 8, 1998, now United States Patent No. 6,331,166; 09/146,185 for "Methods and Apparatus for Securing Medical Instruments to Desired Locations in a Patient's Body," filed on September 1, 1998[.]; 09/159,467 for "Electrosurgical Biopsy Device and Method," filed on September 23, 1998, now United States Patent No. 6,261,241; 09/238,965 for "Tissue Specimen Destruction Device and Method Thereof," filed on January 27, 1999[.]; 09/356,187 for "Electrosurgical Lesion Location Device," filed on July 16, 1999, now United States Patent No. 6,312,429; and 09/477,255 for "Apparatus and Method for Accessing a Biopsy Site," filed on January 4, 2000, all assigned to the assignee of the subject application, which are each hereby incorporated by reference in their entirety, and from each of which priority is claimed under 35 U.S.C. 120.

The paragraph beginning on page 12, line 14:

Figure [2 provides perspective views of the wand shown in Figure 1 with alternate markings;] 2A [shows] is a perspective view of a device with radial wires and

side-cutting wire electrode retracted; Figure 2B [shows] is a perspective view of a device with radial wires extended; Figure 2C [shows] is a perspective view of a device with radial wires and side-cutting electrode extended; and Figure 2D [shows] is a perspective view of a device with the side-cutting electrode extended.

The paragraph beginning on page 12, line 19:

Figure [3 provides perspective views of the wand shown in Figure 1 and a manual handle illustrating features of the invention.] 3A [shows] is a perspective view of a wand with radial wires and side-cutting electrode retracted; Figure 3B [shows] is a perspective view of a wand with radial wires and side-cutting electrode extended[.]; Figure 3C [and 3D are] is a partially cut-away [views] view of a handle embodying features of the invention, showing a plunger mechanism embodying features of the invention with a plunger extended [(3C)]; and [depressed] Figure [(3D)] is a partially cut-away view of a handle embodying features of the invention, showing a plunger mechanism embodying features of the invention with a plunger depressed.

The paragraph beginning on page 13, line 3:

[Figure 4 provides perspective and a partly cut-away perspective views of the distal portion of the wand of Figure 1 embodying features of the invention.] Figure 4A is a partly cut-away perspective view of the distal tip of the wand particularly showing an electrosurgical electrode. Figures 4B and 4C are perspective views of the distal portion of the wand showing extended radial wires and an extended side-cutting electrode illustrating features of the invention.

The paragraph beginning on page 13, line 9:

[Figure 5 provides cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention.] Figures 5A and 5C are longitudinal cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention, and Figures 5B, and 5D-F are transverse cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention.

The paragraph beginning on page 13, line 13:

[Figure 6 provides cross-sectional views of the shaft of the wand of Figure 1 illustrating features of the invention.] Figures 6A and 6C are longitudinal cross-sectional views of the shaft of the wand of Figure 1 embodying features of the invention, and Figures 6B and 6D are transverse cross-sectional views[,] of the shaft of the wand illustrating features of the invention showing a side-cutting electrode in retracted (6A, 6B) and extended (6C, 6D) configurations.

The paragraph beginning on page 13, line 19:

[Figure 8 provides] Figures 8A-8F provide [a] partially cut-away perspective [view] views of a surgeon's disposable unit illustrating features of the invention.

The paragraph beginning on page 14, line 1:

[Figure 10 provides partially cut-away side-views of the wand of Figure 1 embodying features of the invention and transverse cross-sectional views of the wand

and breast tissue during a procedure embodying features of the methods of the invention.] Fig. 10A-10D, and 10G are partially cut-away side-views of the wand of Figure 1 embodying features of the invention. Figs. 10E-10F are transverse cross-sectional views of the wand of Figure 1 embodying features of the invention and breast tissue during a procedure embodying features of the methods of the invention.